

Orthoclinic

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July 18, 2000

Ms. Kathy Eberhart
Food & Drug Administration Center
For Biologics Evaluation & Research
1401 Rockville Pike
Suite 200 North
Rockville, MD 20852-1448HFM42

Dear Ms. Eberhart:

This letter is in response to the Food and Drug Administration's Form on Human Bone Allograft Manipulation and Homologous use in spine and other Orthopaedic reconstruction and repair.

I am an Orthopaedic Surgeon that uses the above referenced tissues in surgery frequently. I feel they offer my patient a safe and cost effective method of providing needed tissues for reconstruction and repair.

I am opposed to further regulation in regard to use of these products due to the fact that human bone products for spine surgery and Orthopaedic surgery has a long history of documented safety and efficacy. Appropriate regulations exist already for donor screening, infectious disease testing and records keeping. Any change in the classification of human bone dowels and other related products from its current status to that of a medical device would severely curtail availability of these products to these physicians and their patients.

I feel that the overall effect of any reclassification of these products to medical devices would have unpredictable implications on the use of other human tissues and would result in a negative impact on the patient care in general.

Please do not hesitate to contact me if you should require further information on my opinion regarding this issue.

Sincerely,

Phillip D. Surface, D.O.

PDS/dh

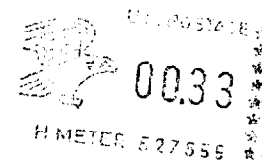
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